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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2015-0011]

Recognizing European Union (EU) and EU Member State Regionalization Decisions for African Swine Fever (ASF) by Updating the APHIS List of Regions Affected with ASF

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: We are advising the public that we are adding European Union (EU) and EU Member State-defined regions of the EU to the Animal and Plant Health Inspection Service (APHIS) list of regions affected with African swine fever (ASF). We will recognize as affected with ASF any region of the EU that the EU or any EU Member State has placed under restriction because of detection of ASF. These regions currently include portions of Estonia, Latvia, Lithuania, and Poland, and all of Sardinia. APHIS will list the EU- and EU Member Statedefined regions as a single entity. We are therefore removing Sardinia as an individually listed region from the APHIS list of ASF affected regions. We are taking this action because of the detection of ASF in Estonia, Latvia, Lithuania, and Poland.

DATES: Effective Date: The addition of the EU- and EU Member State-defined regions to the APHIS list of regions affected with ASF is effective [Insert date of publication in the Federal

<u>Register</u>]. We will consider all comments that we receive on or before [<u>Insert date 60 days after</u> date of publication in the Federal Register].

ADDRESSES: You may submit comments by either of the following methods:

- Federal eRulemaking Portal: Go to
 http://www.regulations.gov/#!docketDetail;D=APHIS-2015-0011.
- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2015-0011, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

Any comments we receive may be viewed at

http://www.regulations.gov/#!docketDetail;D=APHIS-2015-0011 or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

FOR FURTHER INFORMATION CONTACT: Mr. Donald Link, Import Risk Analyst, Regionalization Evaluation Services, National Import Export Services, Veterinary Services, APHIS, 920 Main Campus Drive, Suite 200, Raleigh, NC 27606; (919) 855-7731; Donald.B.Link@aphis.usda.gov.

SUPPLEMENTARY INFORMATION: The regulations in 9 CFR part 94 (referred to below as the regulations) govern the importation of certain animals and animal products into the United States to prevent the introduction of various animal diseases, including rinderpest, foot-and-mouth disease (FMD), bovine spongiform encephalopathy, swine vesicular disease (SVD), classical swine fever (CSF), and African swine fever (ASF). The regulations prohibit or restrict

the importation of live ruminants and swine, and products from these animals, from regions where these diseases are considered to exist.

Sections 94.8 and 94.17 of part 94 of the regulations contain requirements governing the importation into the United States of pork and pork products from regions of the world where ASF exists or is reasonably believed to exist. A list of regions where ASF exists or is reasonably believed to exist is maintained on the Animal and Plant Health Inspection Service (APHIS) Web site at http://www.aphis.usda.gov/import_export/animals/animals_disease_status.shtml.

Currently, the Islands of Sardinia and Malta are the only regions of the European Union (EU) that APHIS lists as affected with ASF. However, ASF outbreaks have recently occurred in domestic and feral swine in portions of Estonia, Latvia, Lithuania, and Poland. The EU has determined that the ASF virus was introduced into these regions from neighboring countries where ASF is present in both the feral and domestic swine populations. The EU has imposed restrictions on the movement of swine and swine products from the regions in which ASF was detected and surrounding regions in the EU. The restrictions and the regions subject to restriction by the EU are listed in the European Commission's Implementing Decision 2014/709/EU.¹

In response to the outbreaks of ASF in Estonia, Latvia, Lithuania, and Poland, APHIS is modifying its list of ASF-affected regions. First, we are adding a new entry that would read "Any restricted zone in the European Union (EU) established by the EU or any EU Member State because of detection of African swine fever in domestic or feral swine." Second, we are

¹ The European Commission is the EU institution responsible for representing the EU as a whole. It proposes legislation, policies, and programs of action and implements decisions of the EU Parliament and Council. Commission Implementing Decision 2014/709/EU is available online at http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32014D0709.

removing Sardinia as an individually listed region. With the addition of this entry to the APHIS list of ASF-affected regions, the APHIS-recognized ASF status of almost any region of the EU would follow the EU and EU Member State restrictions based on ASF detections. Going forward, we would not list each affected region of the EU. We will continue to list Malta individually, which we currently recognize as affected with ASF, but which is not under ASF restrictions by the EU. We are currently evaluating the ASF status of Malta at the request of the EU. If we determine based on our evaluation that the ASF status of Malta should be changed, we will publish our findings and the evaluation for public comment. Adding this entry to the list would subject swine and swine products from EU-restricted regions to APHIS import restrictions designed to mitigate risk of ASF introduction into the United States.

APHIS has previously evaluated the animal health infrastructure, veterinary oversight and legislation, and disease control programs of the EU and individual EU Member States for multiple livestock and poultry species and diseases. Previous APHIS evaluations assessed EU-wide animal health measures and the ability of a Member State to effectively transpose EU animal health regulations into its own veterinary infrastructure and livestock and/or poultry disease control programs. All of the evaluations were conducted in accordance with 9 CFR 92.2, which sets forth the requirements for requesting the recognition of the animal health status of a region as well as for the approval of the export of a particular type of animal or animal product to the United States from a foreign region. Most of the evaluations included a site visit. Through these evaluations, APHIS has analyzed veterinary oversight and animal health infrastructure at both the EU level and the individual Member State level, as well as disease history and vaccination practices for multiple diseases, livestock demographics and traceability practices for multiple species, epidemiologic separation from potential sources of infection, and surveillance

programs, diagnostic laboratory capabilities, and emergency preparedness and response capabilities for multiple livestock and poultry diseases.

Overall, APHIS has consistently concluded that the animal health infrastructure, veterinary oversight and legislation, and corresponding disease control programs are adequate at the EU level. While APHIS evaluations did find unique strengths and weaknesses in individual Member States, overall the findings of these evaluations have been favorable for the Member States. After assessing Member State animal health infrastructure, veterinary oversight and legislation, and disease control programs, and the Member States' ability to transpose and implement EU-level animal health controls, APHIS has taken liberalizing trade action for the EU and certain Member States. APHIS has recognized some Member States as free from FMD, rinderpest, SVD, and/or ASF; evaluated the EU and individual Member States for Newcastle disease and highly pathogenic avian influenza, resulting in APHIS establishing the APHIS-defined EU Poultry Trade Region; and evaluated the EU and individual Member States and other European countries for CSF, resulting in APHIS establishing the APHIS-defined European CSF region.

APHIS recognizing EU and EU Member State regionalization decisions for ASF in the EU is similar to APHIS recognition of EU and Member State regionalization decisions for Newcastle disease and highly pathogenic avian influenza in the EU, and for CSF in the EU and other European countries, and is supported by previous APHIS evaluations of EU Member States for these and other livestock and poultry diseases as described above. In the event that the EU or an EU Member State significantly changes or entirely removes its ASF restrictions or otherwise significantly alters its regulatory framework for ASF, APHIS will conduct an evaluation to

assess the impact of the changes on the risk of ASF introduction into the United States. APHIS

will present for public comment the findings of any such evaluation.

Because the EU- and EU Member State-defined ASF-affected regions includes areas not

currently on the APHIS list of ASF-affected regions, we are adding the new entry to our list

immediately to prevent the introduction of ASF into the United States. We will consider

comments we receive during the comment period for this notice (see DATES above). After the

comment period closes, we will publish another notice in the Federal Register. The notice will

include a discussion of any comments we receive and any changes we are making in response to

the comments.

Authority: 7 U.S.C. 450, 7701-7772, 7781-7786, and 8301-8317; 21 U.S.C. 136 and

136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

Done in Washington, DC, this 26th day of August 2015.

Michael C. Gregoire,

Acting Administrator, Animal and Plant Health Inspection Service.

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